REMARKS

Prior to the present communication, claims 25-30, 55-60 and 85-91 were pending in the subject application, as indicated in the Decision on Appeal that was decided August 28, 2008. The Decision on Appeal has been received and reviewed. All claims stand rejected. In particular, claims 25-30, 55-60, and 85-91 stand rejected under 35 U.S.C. § 103(a), while claims 85-90 stand rejected under 35 U.S.C. § 101. In response, each of the claims 25, 55, 85-89, and 91 has been amended herein, while claim 90 has been canceled and claim 92 has been added. As such, claims 25-30, 55-60, 85-89, 91, and 92 remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Support for Claim Amendments

Each of independent claims 25, 55, and 85 has been amended herein to recite a clarification of processing hereditary data related to the use of clinical agents by a person. In particular, the clarification includes the steps of publishing a graphical user interface (GUI) that is (a) configured to solicit input from a clinician to ascertain whether to authorize performing a genetic test on a patient, wherein the GUI displays fields that reveal an identification of the person and an identification of the genetic test to be performed, and that is (b) configured to receive approval from the clinician to carry out the genetic test via the GUI. Support for these claim amendments may be found in the Specification, for example, at pg. 4, ¶¶ [0033] and [0039]-[0042].

Independent claim 85 has been further amended to recite a clarification of the method for outputting an interpretation of the genetic test result value and the list of risk-associated agents. In particular, outputting includes (a) automatically ordering follow-up tests,

(b) automatically scheduling counseling for the person, (c) automatically storing the interpretation in the person's electronic medical record, and (d) automatically providing a notification in an email addressed to a physician that informs the physician to no longer administer the agent, wherein the physician is identified by the person's electronic medical record. Support for these claim amendments may be found in the Specification, for example, at pg. 5, ¶¶ [0047], [0048], [0059], and [0060].

Independent claim 91 has been amended herein to recite a clarification of the computer system for processing hereditary data related to the use of clinical agents by a person. In particular, the system performs the additional steps of (a) ascertaining whether to automatically generate a low-risk clinical response or a high-risk clinical response based on whether the person has been exposed to an agent on the list of risk-associated agents, (b1) if the person has been exposed to the agent on the list of risk-associated agents, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents, otherwise, (b2) automatically generating the low-risk clinical response that includes adding a comment to the person's electronic medical record indicating that no risks were determined from the genetic test result value. Support for these claim amendments may be found in the Specification, for example, at pg. 6, ¶¶ [0055]-[0057].

In general, amendments to the claimed subject matter are not "new matter" within meaning of 35 U.S.C. § 132 or Rule 118 of Patent Office Rules of Practice, unless they disclose an invention, process, or apparatus not theretofore described. Further, if later-submitted material

simply clarifies or completes prior disclosure, it cannot be treated as "new matter."[1] By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, "a patent application *necessarily discloses* that function, theory or advantage, even though it says nothing explicit concerning it" (emphasis added).[2] The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.[3] Accordingly, because these amendments are explicitly discussed, and/or inherent to, the procedure of processing hereditary data related to the use of clinical agents by a person, as memorialized in the Detailed Description, the newly recited subject matter is encompassed by the scope of the Specification and does not constitute new matter.

In addition, the Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.[4] As such, in rejecting a claim for introducing new matter, the Examiner must set forth express findings of fact which support the lack of written description conclusion.[5]

Rejections based on 35 U.S.C. § 101

Claims 85-90 stand rejected under 35 U.S.C. § 101 for being directed toward non-statutory subject matter. In particular, it is stated in the Decision on Appeal at page 9, ¶ 5 that claims 85-90 are directed to "computer-readable media," which is interpreted to include a carrier

[1] *Triax Co. v Hartman Metal Fabricators, Inc.*, 479 F2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).
[2] *See* MPEP § 2163.07; *In re Reynolds*, 443 F.2d 384 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376 (CCPA 1973).
[3] *See id.*
[4] *In re Wertheim*, 541 F.2d at 263.
[5] MPEP § 2163.04(I).

wave. Based on the inclusion of the carrier wave, the Board of Patent Appeals and Inferences concluded that independent claim 85, and the claims that depend therefrom, are not within any of the four categories of statutory subject matter.

In response, claim 85 has been amended herein to recite, in part, "computer storage media having computer-executable instructions embodied thereon that, when executed, perform a method." "When functional descriptive material is recorded on some computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since the use of technology permits the function of the descriptive material to be realized."[6] As claim 85 is now directed to computer-executable instructions embedded on "computer storage media" that stores a data structure, the claim constitutes physical articles that fall within the statutory classes. That is, amended claim 85 relates to media encoded with a data structure that defines structural and functional interrelationships between the data structure of the computer software and hardware components. This permits the data structure's functionality to be realized.

Accordingly, it is respectfully submitted that amended claim 85 is limited to tangible embodiments and, thus, is directed toward statutory subject matter. Further, each of claims 86-89 are believed to be in condition for allowance based, in part, upon their dependency from independent claim 85, and such favorable action is respectfully requested.

[6] MPEP § 2106.01. *See*, *In re Lowry*, 32 F.3d 1579, 1583-84 (Fed. Cir. 1994) (discussing patentable weight of data structure stored on a computer readable medium that increases computer efficiency); s*ee also*, *In re Warmerdam*, 33 F.3d 1354, 1360-61 (discussing patentable weight of data structure limitations in the context of a statutory claim to a data structure stored on a computer readable medium that increases computer efficiency).

35 U.S.C. § 103 Obviousness Rejections based on Ichikawa (Internal Medicine (July 2000) Vol. 39, no. 7, pp. 523-524) in view of Evans (Science (Oct. 1999) Vol. 286, pp. 487-491) and U.S. Patent Application Publication No. 2002/0049772 to Reinhoff

Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 stand rejected under 35 U.S.C. § 103(a) as being obvious over an article entitled "Single Nucleotide Polymorphism to Disclose Sever Side-effects or Proper Dosage for Each Patient" submitted by Ichikawa to INTERNAL MEDICINE, published in July 2000, Vol. 39, no. 7, pp. 523-524 (hereinafter the "Ichikawa reference"), in view of an article entitled "Pharmacogenomics: Translating Functional Genomics into Rational Therapeutics" submitted by Evens to SCIENCE, published in Oct. 1999, Vol. 286, pp. 487-491 (hereinafter the "Evans reference"), and in further view of U.S. Patent Application No. 2002/0049772 to Reinhoff reference (hereinafter the "Reinhoff reference"). As the Ichikawa reference, the Evans reference, and the Reinhoff reference, whether taken alone or in combination, fail to teach or suggest all of the limitations and elements of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth. Further, claim 90 has been canceled by way of the present communication and, accordingly, the rejection of this claim has been rendered moot. However, the subject matter recited by the previously pending claim 90 is incorporated as an amendment to claim 85.

Independent claims 25, 55 and 85, as amended herein, recite a method, a computer system, and computer storage media, respectively, for processing hereditary data related to the use of clinical agents by a person. This method includes, *inter alia*, "publishing a graphical user interface (GUI) that is configured to solicit input from a clinician to ascertain whether to authorize performing a genetic test on a patient," where "the GUI displays fields that reveal an identification of the person and an identification of the genetic test to be performed." The GUI is further configured to (a) receive approval from the clinician to carry out the genetic

test, and (b) to receive a result value of the genetic test for the person. In this way, a physician is provided with a GUI display (e.g., on a monitor) that inquires whether to perform the genetic test by providing certain pieces of information.

The Ichikawa and Evans reference are cited for determining a drug dosage based on genetic testing that relates polymorphisms to atypical clinical events,[7] and providing a computerized table showing these atypical clinical events,[8] respectively. However, these references, as cited, do not apply the table of atypical clinical events to the context of a medical setting. That is, Ichikawa and Evans do not consider asking a physician to order a genetic test, via a GUI supported by a computer system, by revealing both an identification of a person and an identification of the genetic test to be performed on the person. In operation, the identifications provided by the GUI may be utilized by the physician for determining whether to order the genetic test. As claimed, the result values yielded by the genetic test are queried against the computerized table listing polymorphism values and atypical clinical events.

The description in Reinhoff reference fails to cure these deficiencies of Ichikawa and Evans. Instead, Reinhoff describes creating a database where users are free to submit a biological sample to render phenotypic data.[9] In this way, the Reinhoff reference does not include the publishing a GUI configured to solicit and receive inputs from a clinician.

Accordingly, it is respectfully submitted that the Ichikawa, Evans, and Reinhoff references, whether taken alone or in combination, fail to teach or suggest all of the elements of the claims 25, 55, and 85. Consequently, for at least the reasons stated above, Applicants contend that these independent claims are in condition for allowance, and submit that the

[7] *See Ichikawa reference* at pg. 523, col. 2, ¶ 3.
[8] *See Evans reference* at pg. 490, col. 3, ¶ 2.
[9] *See Reinhoff reference* at pg. 4, ¶ [0038].

rejections thereof under §103(a) are overcome and should be withdrawn. Such actions are respectfully requested. Each of claims 26-30, 56-60, 86-89, and 92, which depend from one of amended claims 25, 55, and 85, is submitted to be allowable, at a minimum, by virtue of their dependence from an allowable base claim.[10]

New claim 92, which depends from amended independent claim 25, is allowable for the following reasons, in addition to its dependence from claim 25. Claim 92 recites processing heredity data by providing a GUI that informs a physician of attributes of the genetic test prior to an order for the test. The process of informing includes "accessing the person's demographic information stored the electronic medical record," "utilizing the demographic information in cooperation with the computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values to determine a likelihood of a genetic variation existing in the person and a severity of an atypical event associated with the genetic variation," and "publishing the GUI based on determined likelihood and severity." As discussed above, the cited reference does not describe displaying a GUI to a physician to facilitate ordering a genetic test on the person. *A fortiori*, the cited references do not render obvious a process of making a determination to ask the physician, via the GUI, whether to order the genetic test. As such, for at least the reasons indicated immediately above, claim 92 is contended to be in condition for allowance, and such favorable action is respectfully requested.

Further, independent claim 85, as amended herein, recites processing hereditary data via a method that includes, *inter alia*, "outputting an interpretation of the genetic test result value and the list of risk-associated agents," where outputting includes (a) "automatically ordering follow-up tests, (b) automatically scheduling counseling for the person, (c)

[10] *See* 37 C.F.R. § 1.75(c) (2006).

automatically storing the interpretation in the person's electronic medical record, and (d) automatically providing a notification in an email addressed to a physician that informs the physician to no longer administer the agent, wherein the physician is identified by the person's electronic medical record. In this way, outputs (a)-(d) are each automatically generated upon performing a determination of whether the genetic test result value is a polymorphism value associated with an atypical clinical event.

The Ichikawa, Evans, and Reinhoff references, as cited, do not describe this practical implementation of a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. As discussed above, these references, fail to apply the table of atypical events to the context of a medical setting as claimed. That is, the Ichikawa, the Evans, and the Reinhoff references, as cited, do not consider each of the outputs (a)-(d). Accordingly, it is respectfully submitted that the Ichikawa, Evans, and Reinhoff references, whether taken alone or in combination, fail to teach or suggest all of the elements of the claim 85. Consequently, for at least the reasons stated above, Applicants contend that the independent claim 85 is in condition for allowance, and submit that the rejections thereof under §103 are overcome and should be withdrawn. Such actions are respectfully requested. Each of claims 86-89, which depend from amended claim 85, is submitted to be allowable, at a minimum, by virtue of their dependence from an allowable base claim.[11]

Independent claim 91, as amended herein, recites a computer system for processing hereditary data via a method that includes, *inter alia*, "ascertaining whether to automatically generate a low-risk clinical response or a high-risk clinical response based on whether the person has been exposed to an agent on the list of risk-associated agents," "if the

[11] *See* 37 C.F.R. § 1.75(c) (2006).

person has been exposed to the agent on the list of risk-associated agents, automatically generating the high-risk clinical response that includes suspending an order for the agent and placing an alternative order for an agent that is absent from the list of risk-associated agents," otherwise, "automatically generating the low-risk clinical response that includes adding a comment to the person's electronic medical record indicating that no risks were determined from the genetic test result value." In this way, particular clinical responses are invoked based on whether an person is exposed to an agent on the list of risk-associated agents.

The Ichikawa, Evans, and Reinhoff references, as cited, do not describe this implementation of generating clinical responses to protect a person (e.g., patient) from ascertained risks. Moreover, the cited references do not consider a hierarchy of risks (e.g., high and low levels), and do not consider certain actions attached to each of the risks. As discussed above, these references, fail to apply the table of atypical events to the context of a medical setting as claimed. That is, Ichikawa, Evans, and Reinhoff reference do not consider an assessment of risks and an appropriate response once the table is queried and patient information is compared against the results of the query. Accordingly, it is respectfully submitted that the Ichikawa, Evans, and Reinhoff references, whether taken alone or in combination, fail to teach or suggest all of the elements of the claim 91. Consequently, for at least the reasons stated above, Applicants contend that the independent claim 91 is in condition for allowance, and submit that the rejections thereof under §103 are overcome and should be withdrawn. Such actions are respectfully requested.

35 U.S.C. § 103 Obviousness Rejections based on the Ichikawa reference, in view of the Evans reference, the Reinhoff reference, and U.S. Patent Application No. 2002/003822 to Fey

Claims 28, 58 and 88 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference, in view of the Evans reference, the Reinhoff reference, and U.S. Patent Application No. 2002/003822 to Fey (hereinafter the "Fey reference"). As the cited references, whether taken alone or in combination, fail to teach or suggest all of the limitations and elements of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

As discussed above, neither the Ichikawa reference, the Evans reference, nor the Reinhoff reference teach or suggest all of the limitations of independent claims 25, 55, and 85 (as amended herein), from one of which each of rejected claims 28, 58, and 88 depends. It is respectfully submitted that the Fey reference fails to cure at least the above-discussed deficiencies of the above-cited references. More particularly, the Office cites to the Fey reference for discussing an electronic database that includes clinical information.[12] However, the electronic database is not managed by the processes claimed, and is not automatically applied in the medical setting recited in the amended claims 25, 55, and 85. Accordingly, it is respectfully submitted that the Ichikawa, Evans, Reinhoff, and Fey references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the amended independent claims 25, 55, and 85 and, accordingly, of claims 28, 58, and 88.[13]

[12] *See Fey Reference* at FIG. 5A.
[13] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, each of claims 25-30, 55-60, 85-89, 91, and 92 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2179 or via email at jdickman@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action.

It is believed that no fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.83071.

Respectfully submitted,

/JEAN M. DICKMAN/

Jean M. Dickman
Reg. No. 48,538

BPT/tq
SHOOK, HARDY & BACON L.L.P.
2555 Grand Blvd.
Kansas City, MO 64108-2613
816-474-6550